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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/777,496

02/12/2004

Christopher Charles Andrews

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01/02/2008

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EXAMINER

LANG, AMY T

ART UNIT

PAPER NUMBER

3731

NOTIFICATION DATE

DELIVERY MODE

01/02/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

e-OfficeActionBSc@faegre.com

Office Action Summary

Application No.

10/777,496

Applicant(s)

ANDREWS ET AL.

Examiner

Amy T. Lang

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11 is/are pending in the application.
- 4a) Of the above claim(s) 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 06/22/2005, 05/14/2004.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-9 and 11, in the reply filed on 10/18/2007 is acknowledged.
2. Claim 10 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/18/2007.

Claim Objections

3. **Claim 8** is objected to because of the following informalities: Claim 8, which depends from claim 4, recites "wherein the nose extends from the smaller diameter portion of the distal segment." However, claim 4 does not recite a smaller diameter portion of the distal segment. Therefore, there is insufficient antecedent basis for this limitation in the claim. Appropriate correction is required.
4. **Claims 5 and 6** are objected to because of the following informalities: Claims 5 and 6 recite "rearward" and "forward" to describe relative locations of the claimed components. However, it is the examiner's position that these references are confusing since rearward typically refers to a distal area and forward to a proximal area. Since this is opposite in the instant claims and specification, it is the examiner's position that the claims are confusing. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. **Claim 9** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 9 there exists an inconsistency between the language in the preamble and that of the claim body, thus making the scope of the claim unclear. In the preamble, lines 1-4, applicant recites "an assembly for removing a guide catheter from about a cardiac lead" with the guide catheter and pacemaker lead being only functionally recited, i.e. "for removing", thus indicating that the claim is directed to the subcombination, the assembly. However, in lines 3-5, applicant positively recites the guide catheter and the peacemaker lead as part of the invention, i.e. "including a lumen" and "including a distal end and terminal end, with a lead body", this indicating that the combination, the assembly with the guide catheter and pacemaker lead, is being claimed. As such it is unclear whether applicant intends to claim the subcombination or the combination. Applicant is hereby required to indicate to which, subcombination or combination, the claims are intended to be directed, and amend the claims such that the language thereof is consistent with this intent. For examination purposes, only the subcombination will be examined on the merits.

Claim Rejections - 35 USC § 102

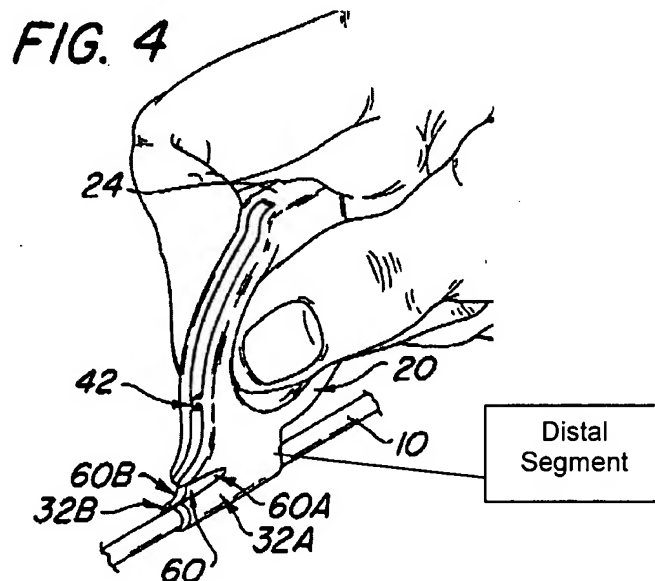
7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

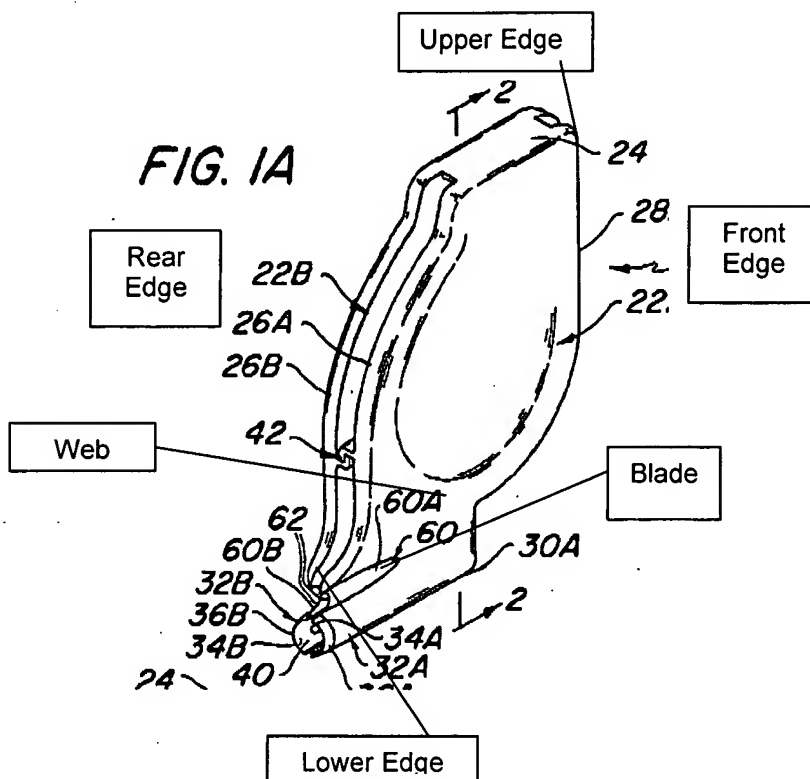
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. **Claims 1-4 and 9** are rejected under 35 U.S.C. 102(b) as being anticipated by Brenner (US 6,497,681 B1).

With regard to **claims 1 and 9**, Brenner discloses a device for removing a guide catheter from a linear lead (see entire document). The device comprises a body (20) having a front, rear, upper, and lower edge. As shown in Figure 4, Brenner discloses a central opening that is sized to engage the linear lead and therefore clearly overlaps the instantly claimed distal segment (column 5, line 66 through column 6, line 6).



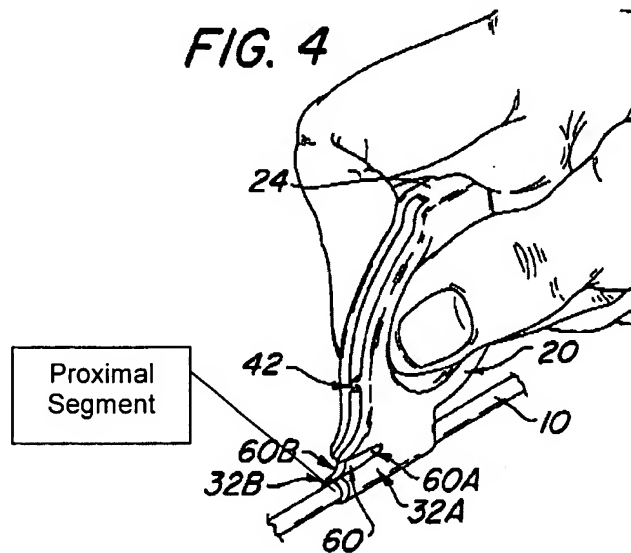
Brenner further discloses a blade (60) mounted between the lower edge and the distal segment and supported by a web extending from a segment between the lower edge and the distal segment (column 7, line 61 through column 8, line 10).



The blade comprises a first and second cutting portion (60A and 60B), wherein each is angled from the front edge toward the rear edge (Figure 11). A notch is formed between the two blade tips (Figure 1A).

With regard to **claim 2**, as shown in Figure 1A the notch is positioned close to the distal segment and therefore clearly overlaps the instantly claimed proximate.

With regard to **claim 3**, Brenner also discloses an arcuate side opening forming a central opening and therefore overlaps the instantly claimed proximal segment. As shown below, the linear lead is inserted through the proximal segment central opening.



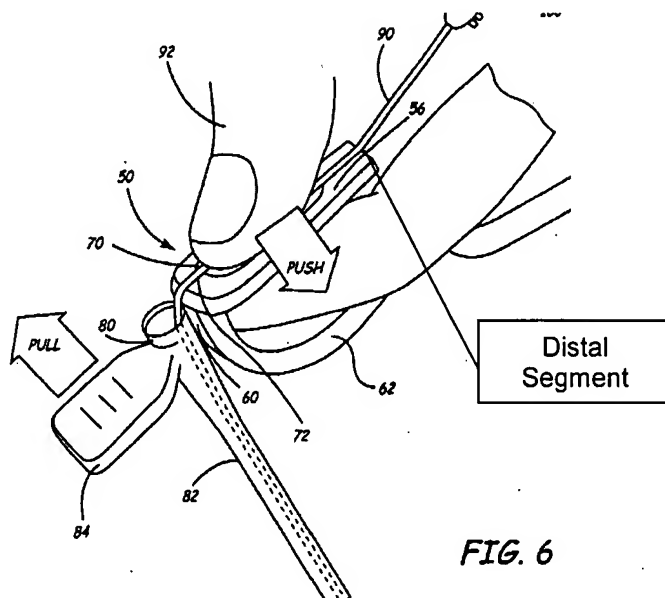
With regard to claim 4, the distal segment opening is arcuate and sized to receive the linear lead (Figure 4).

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

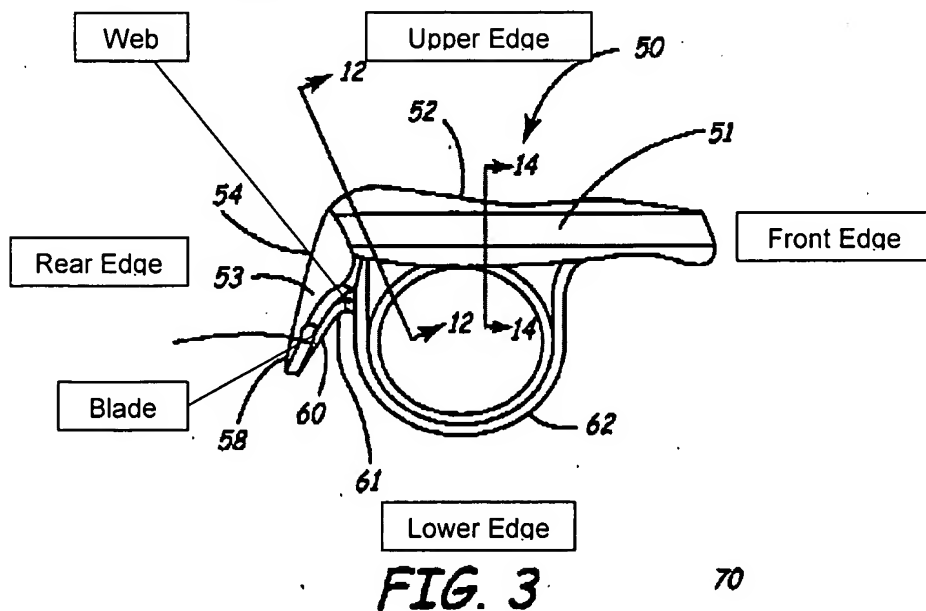
9. **Claims 1-4, 8, 9, and 11** are rejected under 35 U.S.C. 102(e) as being anticipated by Gardeski (US 2003/0181935 A1).

With regard to **claims 1 and 9**, Gardeski discloses a device for removing a guide catheter from a linear lead (see entire document). The device comprises a body (51) having a front, rear, upper, and lower edge. As shown in Figure 4, Gardeski discloses a

central opening (72) that is sized to engage the linear lead and therefore clearly overlaps the instantly claimed distal segment ([0050]; Figure 6).



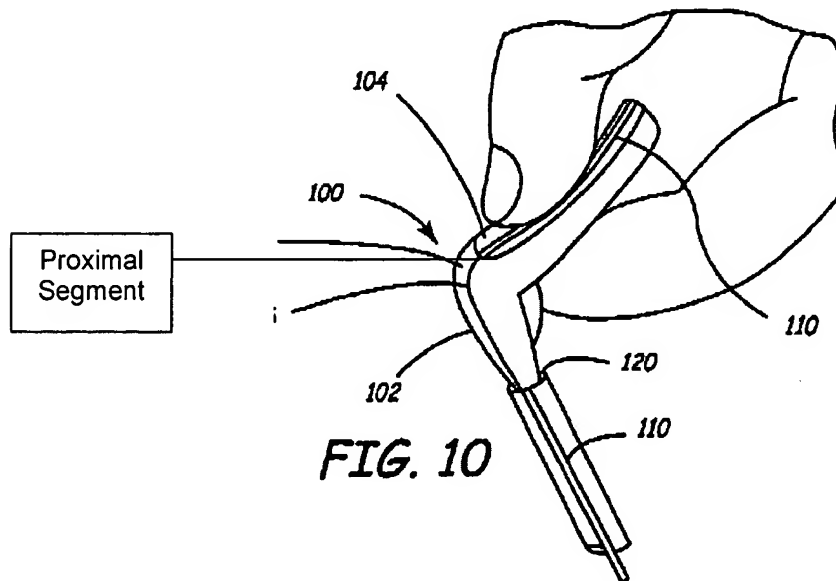
A blade (60) is mounted between the lower edge and the distal segment and supported by a web extending from a segment between the lower edge and the distal segment (column 7, line 61 through column 8, line 10).



The blade is further disclosed as having a sawtooth configuration, which clearly overlaps the first and second cutting portions ([0045]). Further, a notch would be present between each cutting portion.

With regard to **claim 2**, since the cutting blade (60) is positioned close to the distal segment and comprises the notch, it is the examiner's position that the notch is proximate the distal segment (Figure 3).

With regard to **claim 3**, Gardeski also discloses an arcuate side opening forming a central opening and therefore overlaps the instantly claimed proximal segment.



With regard to **claim 4**, the distal segment opening is arcuate and sized to receive the linear lead (Figure 6).

With regard to **claim 8**, Gardeski discloses a nose (53) extending from the distal segment and adapted to be inserted within the guide catheter (Figure 3; [0047]).

With regard to **claim 11**, Gardeski discloses laterally opposing wings, one of which is shown below.

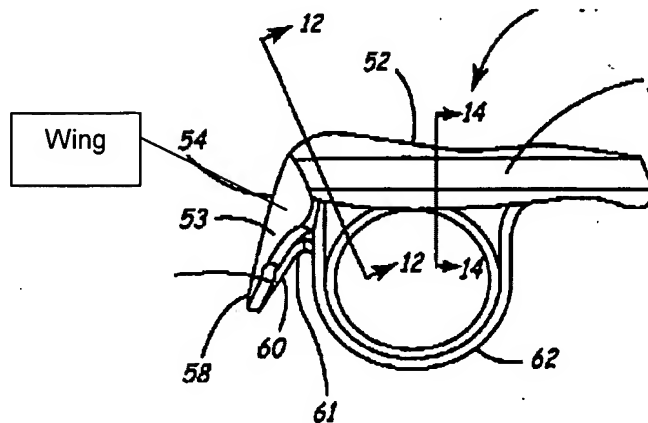


FIG. 3

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. **Claims 5-7** are rejected under 35 U.S.C. 103(a) as being unpatentable over Gardeski (US 2003/0181935 A1).

With regard to **claim 5**, Gardeski discloses a device for removing a guide catheter from a linear lead comprising a proximal and a distal segment. Gardeski further teaches wherein channel (72), which runs through the proximal and distal segments, varies in size and shape along the length of the channel. Although Gardeski does not specifically disclose wherein the distal segment has a forward smaller diameter and a rearward larger diameter, since this limitation is within the scope of Gardeski, it would have been obvious to one of ordinary skill at the time of the invention for the distal segment of Gardeski to have a forward smaller diameter and a rearward larger diameter.

With regard to **claim 6**, Gardeski discloses laterally opposing wings, one of which is shown below.

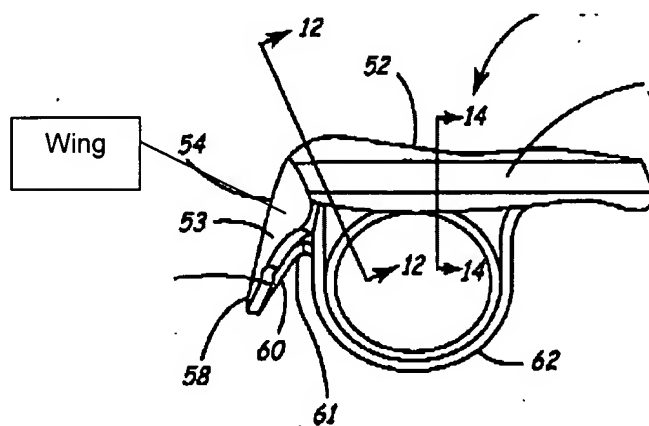


FIG. 3

With regard to **claim 7**, it is also the examiner's position that when the distal segment comprises a forward smaller diameter and a rearward larger diameter, a transition point would be created between these two segments. As shown in Figure 3, the wings would be close to the transition point and therefore adjacent.

Conclusion

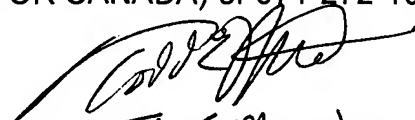
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy T. Lang whose telephone number is 571-272-9057. The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

12/17/2007

ARL


Todd E. Manahan
SPE 3731